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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,637	12/19/2001	Michael Birsha Davies	PG3693USW	4268

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GLAXOSMITHKLINE  
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RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER
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ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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**Office Action Summary**

Application No.

10/031,637

Applicant(s)

DAVIES ET AL.

Examiner

Shumaya B. Ali

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-25 and 27-41 is/are pending in the application.
- 4a) Of the above claim(s) 2-7,9-15,29-31 and 34-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,16-25,27,28,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of Claims*

Claims 1-7,9-25, and 27-41 are pending in the current application. Claims 2-7,9-15,29-31,35-41 indicated withdrawn in the reply filed on 11/9/2006. Claim 34 is withdrawn because it depends from a withdrawn claim 10. Claims 8 and 26 are cancelled.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Election/Restrictions*

Applicant's timely traversal of restriction requirement between species 4 and 5 in the reply filed on 11/9/2006, see remarks filed on 11/9/06, page 5 lines 3-6 found persuasive, therefore, claims corresponding to species 5 would be examined.

Claims 3,4,6,7,9,29-31, and 35-41 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/9/2006.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1,16-25,27, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

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Claim 1 recites the limitation "the ends" in line 6. There is insufficient antecedent basis for this limitation in the claim.

As to claim 16, metes and bounds of claim are vague. It is unclear whether "multi-unit form" is limited by the claim since the later limitation, "a series arrangement of a plurality of carriers" cited after the transition phrase "comprising". Should "multi-unit form" be limited, then claim may require proper structure limiting "multi-unit form".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, and 16-25 are rejected under 35 U.S.C. 102(b) as being anticipated by**

**Groves US 3,482,733**

**As to claim 1**, Groves discloses a carrier comprising an elongate strip (fig.3, 24,25) having a first portion (24) and a second portion (25), a fold (see labeled fig.3 attached below) between said first portion and said second portion such that the first portion contacts the second portion (see fig.3); and a join (see "seal", col.3 lines 71 and 72) between the first portion and the second portion, wherein said join and the fold form the edges of a pocket or pouch (fig.3, 20) for containment of medicament, said pocket or pouch containing a unit dose of medicament (fig.2, 16) therein and, wherein the ends of the elongate strip form a pair of pull release tabs (fig.3, 18,19, see also col.1 lines 20-24), each of said release tabs having at least one perforation (22,23,

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see also “perforations extend within the edge portions between the compartments” in col.1 line 15) formed therein.

**As to claim 16,** Groves discloses a carrier according to claim 1 comprising a series arrangement of a plurality of carriers (see fig.3).

**As to claim 17,** Groves discloses wherein each of said plurality of carriers is connected together (see fig.3).

**As to claim 18,** Groves discloses wherein each of said plurality of carriers is formable from the same elongate strip (see fig.3).

**As to claim 19,** Groves discloses wherein said strip has a point of weakness (see labeled fig.3) between each carrier in said series arrangement.

**As to claim 20,** Groves discloses wherein each pocket or pouch is foldable to flat alongside the elongate strip (see fig.5).

**As to claim 21,** Groves discloses wherein the elongate strip is flexible (see “flexible” in col.1 line 10).

**As to claim 22,** Groves discloses wherein the elongate strip comprises material selected from the group consisting of metal foil, an organic polymeric material and paper (see “polio film” or “wax paper” in col.3 lines 30-35).

**As to claim 23,** Groves discloses wherein the strip comprises a laminate (see “adhesive” in col.3 line 35).

**As to claim 24,** Groves discloses wherein the join is formable by a joining method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp, pressure and ultrasonic sealing (col.3 lines 30-35).

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As to claim 25, Groves discloses wherein the join is peelable to enable peelable access to the pocket or pouch (see fig.5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 27,28,32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groves US 3,482,733.**

**As to claim 27**, Groves discloses the claimed invention as applied to claim 1, however lacks wherein said medicament is in dry powder, tablet, liquid, paste, cream or capsular form; and **as to claim 28**, Groves discloses the claimed invention as applied to claim 1, however lacks wherein said medicament is selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate, and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof. However, Groves teaches the pocket/pouch can be filled with articles or pellets (fig.2, 16; col.3 lines 55 and 56). Therefore, it would have been obvious to one of ordinary skill in the art to broadly consider the teachings of articles or pellets as medicament, furthermore consider the specific type of medicament contained in the pocket/pouch as an obvious matter of design choice because Applicant has not established why a specific medicament as cited in claim 28 would have provided an advantage, used for a particular purpose, or solved a stated problem. Therefore, it would have been an obvious matter of design choice to modify Groves to obtain the invention as specified in claims 27 and 28.

**As to claims 32 and 33**, Groves lacks the detailed method steps as claimed, however, teaches structures such as a carrier comprising a fold between a first portion and second portion of an elongate strip such that the first portion contacts said second portion forming a join between said first portion and said second portion wherein said join and the fold form the edges of an open pocket or pouch, and join as cited applied in claim 1. Groves further lacks the method steps of filling said open pocket or pouch with a unit dose of medicament. However, Groves teaches the pocket/pouch can be filled with articles or pellets (fig.2, 16; col.3 lines 55 and 56),

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therefore broadly teaches it would have been obvious to fill the pocket/pouch with medicament. Since Groves teaches structures to perform the method steps cited in claims 32 and 33, it would have been obvious to one of ordinary skill in the art to obtain method as claimed using the carrier of Groves.

### ***Claim Objections***

Claims filed on 11/9/06 are objected for minor informalities: claims are not legible. Appropriate correction is required.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Feldstein (US 4,274,550) and Glassman (US 3,698,549) are cited to teach carrier within the scope of the claimed invention.

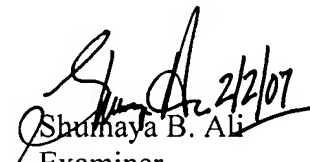
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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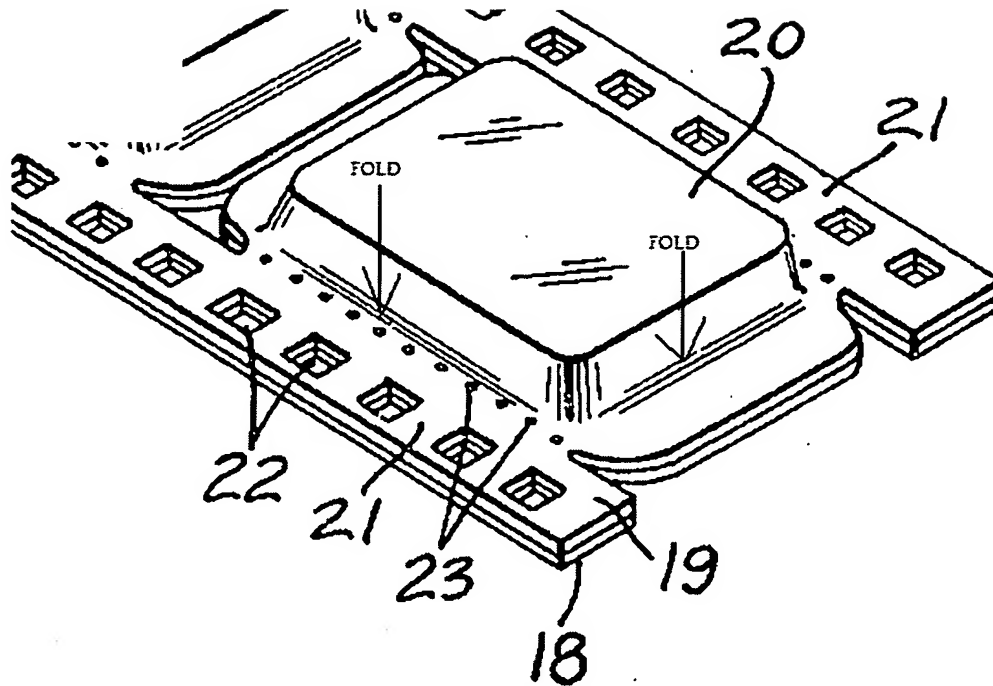
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Shumaya B. Ali  
Examiner  
Art Unit 3771

  
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SUPERVISORY PATENT EXAMINER  
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2/5/07

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Prior Art  
figure 3  
Groves US 3,492,733

*Shing Arc*  
2/2/07